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| 10/603,865 | 06/26/2003 | John Kevin Collins | 1377-0188P | 1455 |

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| EXAMINER |
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MARX, IRENE

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/603,865 | Applicant(s) COLLINS ET AL. | |
| | Examiner Irene Marx | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

The status of the parent case(s) should be updated.

The information disclosure statement filed 7/28/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The U.S. patents have been considered. It has been placed in the application file, but the information referred to therein has not been considered.

Applicant's election with traverse of Group I, claims 1,2, 5 and 7 on 12/22/05 is acknowledged. The traversal is on the ground(s) that no lack of unity was found in the PCT and alleged circular reasoning was found in the restriction requirement. However, the criticized phrase containing alleged circular reasoning is taken out of context. The criticized phrase is followed by the following phrase: "The compositions of the various groups would be expected to have distinct morphological, functional and physiological properties as evidenced by divergent classification, process of making and process of using." This statement is not addressed.

Regarding lack of unity, it is respectfully noted that the instant application is not filed under 35 U.S.C § 371. In any event, the actions taken in a PCT application are not binding on U.S. filed applications.

Regarding the question of burden, an undue burden would ensue from the examination of multiple compositions which have distinct characteristics and a process of use. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

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Claims 1, 2, 5-7 are being considered on the merits. Claims 5-7 are being considered to the extent that they pertain to the inventions of claim 1 and 2. The claims should be amended accordingly.

Claims 3-4 and 8 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 5-7 are rejected under 35 U.S.C. 101 because the claim reads on a product that is found in nature and thus, is unpatentable to applicant. It is suggested that applicant use the language "purified" or "isolated" in connection with the agent to identify a product that is not found in nature. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in that it is unclear what is intended by "isolated from resected and washed human gastrointestinal tract". Is the whole tract intended? If a portion is intended, which portion, i.e., the mouth, esophagus, stomach, colon, rectum, duodenum, etc..

Claim 1 is confusing in the recitation of "said activity being produced only by growing cells and being destroyed by proteinase K and pronase E". Is the activity or are the cells or both

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destroyed by proteinase K and pronase E? Claim 1 is vague and indefinite in that fails to find proper internal antecedent basis for “said activity”.

Claim 1 is confusing in the recitation of “which has bacteriocins-like properties”, because the antecedent basis for this phrase is not clearly delineated. Does it refer to “human gastric juice”, “agent”, “supernatant”, “activity”, or “strain of *Lactobacillus salivarius*” etc.

Claim 1 is vague and indefinite in that the nature of “its secretory products” is not clearly delineated in the claim or specification. This recitation covers all possible products secreted by any *L. salivarius*. In addition, the intended antecedent basis of “being maintained in the presence of physiological concentrations of human bile and human gastric juice, which has bacteriocins-like properties” is unclear. In other words, the nature of what is “maintained” cannot be readily assessed.

Claim 2 is vague, indefinite and confusing in that there is no indication as to how the “apparent” molecular weight is determined. The claim is further confusing in that the standards to score for “sensitivity” or “resistance” are not set forth with any particularity. For example, the concentration of the challenging solvent or enzyme is not delineated. In addition, it is unclear what “resistance over wide pH range” entails.

Claims 5-7 are incomplete as depending on non-elected claims.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 5-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel strains of *L. salivarius* which are required to obtain a specific product. It is not clear if the written description is sufficiently repeatable to

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avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 4 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

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Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Flynn *et al.* ..

The claims are directed to a product having antimicrobial activity produced by a *L. salivarius* strain and having certain properties.

Flynn *et al.* disclose a product having antimicrobial activity produced by a *L. salivarius* strain and having certain properties, which is the same as the disclosed product. See, e.g., Abstract; Specification, page 4.

The disclosed agent would be suitable for the intended uses of claims 5-7.

Claims 1,2 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Arihara *et al.* (Lett. Appl. Microbiol. **22(6)**:420-424).

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The claims are directed to a product having antimicrobial activity produced by a *L. salivarius* strain and having certain properties.

Arihara *et al.* disclose various product having antimicrobial activity produced by *L. salivarius* strains, which are destroyed by proteinases and which have bacteriocins-like properties. The properties indicated at claim 2 are not specifically disclosed, but are inherent in at least one of the products disclosed. See, e.g., Tables 1 and 2.

The disclosed agent would be suitable for the intended uses of claims 5-7 at least to some extent.

Claims 1, 2 and 5-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ten Brink *et al.*

The claims are drawn to an antimicrobial agent which has been isolated from *L. salivarius* and which has certain properties.

The cited reference discloses an antimicrobial product produced by a *Lactobacillus* strain which appears to be identical to the presently claimed product (see, e.g., page 144, table 1) since its activity is destroyed by a protease such as trypsin and has an apparent molecular weight of about 30 kDA, is moderately heat stable, is resistant over a wide pH range. The product has a broad spectrum antimicrobial activity. The referenced agent appears to be identical to the presently claimed agent and is considered to anticipate the claimed agent since it is likely to be resistant to the same enzymes as recited due to its proteinaceous nature. The intended uses of the product would be the same. Consequently, the claimed product appears to be anticipated by the reference.

In the alternative, even if the claimed agent is not identical to the referenced compound with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced agent is likely to inherently possess the same characteristics of the claimed agent particularly in view of the similar characteristics which they have been shown to share. Thus the claimed product would have been obvious to those skilled in the art within the meaning of USC 103.

The disclosed agent would be suitable for the intended uses of claims 5-7 at least to some extent.

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Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651